### § 1002.2 [Reserved]

### § 1002.3 Notification to user of performance and technical data.

As authorized by § 5.90 of this chapter, the Director and Deputy Director of the Center for Devices and Radiological Health may require a manufacturer of a radiation emitting electronic product to provide to the ultimate purchaser, at the time of original purchase, such performance data and other technical data related to safety of the product as the Director or Deputy Director finds necessary.

[60 FR 48385, Sept. 19, 1995; 61 FR 13424, Mar. 27, 1996]

### § 1002.4 Confidentiality of information.

The Secretary or his representative shall not disclose any information reported to or otherwise obtained by him, pursuant to this part, which concerns or relates to a trade secret or other matter referred to in section 1905 of title 18 of the United States Code, except that such information may be disclosed to other officers or employees of the Department and of the other agencies concerned with carrying out the requirements of the Act. Nothing in this section shall authorize the withholding of information by the Secretary, or by any officers or employees under his control, from the duly authorized committees of the Congress.

### § 1002.7 Submission of data and reports.

All submissions such as reports, test data, product descriptions, and other information required by this part, or voluntarily submitted to the Director, Center for Devices and Radiological Health, shall be filed with the number of copies as prescribed by the Director, Center for Devices and Radiological Health, and shall be signed by the person making the submission. The submissions required by this part shall be addressed to the Center for Devices and Radiological Health, Electronic Product Reports, Office of Compliance (HFZ–307), 2098 Gaither Rd., Rockville, MD 20850.

(a) In addition to the requirements of this part, all material submitted to the Director, Center for Devices and Radiological Health, shall be submitted pursuant to the provisions of part 20—Public Information, of this chapter.

(b) Where guides or instructions have been issued by the Director for the submission of material required by this part, such as test data, product reports, abbreviated reports, supplemental reports, and annual reports, the material submitted shall conform to the applicable reporting guides or instructions. Where it is not feasible or where it would not be appropriate to conform to any portion of a prescribed reporting guide or instruction, an alternate format for providing the information requested by that portion of the guide or instruction may be used provided the submitter of such information submits adequate explanation and justification for use of an alternate format. If the Director, Center for Devices and Radiological Health, determines that such justification is inadequate and that it is feasible or appropriate to conform to the prescribed reporting guide or instruction, he may require resubmission of the information in conformance with the reporting guide or instruction.

(c) Where the submission of quality control and testing information is common to more than one model, or model family of the same product category, a ''common aspects report'' consolidating similar information may be provided, if applicable.

[42 FR 18062, Apr. 5, 1977, as amended at 53 FR 11254, Apr. 6, 1988; 60 FR 48385, Sept. 19, 1995]

## Subpart B—Required Manufacturers' Reports for Listed Electronic Products

SOURCE: 60 FR 48386, Sept. 19, 1995, unless otherwise noted.

### § 1002.10 Product reports.

Every manufacturer of a product or component requiring aproduct report as set forth in table 1 of § 1002.1 shall submit a product report to the Center for Devices and Radiological Health, Electronic Product Reports, Office of Compliance (HFZ–307), 2098 Gaither Rd., Rockville, MD 20850, prior to the introduction of such product into commerce. The report shall be distinctly